

# Bereskin & Parr

INTELLECTUAL PROPERTY LAW

Appl. No : N/A Confirmation No.:  
Applicant : Bradley L. Urquhart et al.  
Filed : Filed Concurrently Herewith  
Title : METHOD OF TREATING ELEVATED PLASMA HOMOCYSTEINE  
LEVELS IN ESRD PATIENTS  
TC./A.U. : N/A  
Examiner : N/A  
  
Docket No. : 10935-35  
Customer No. : 001059

Honorable Commissioner for Patents  
P. O. Box 1450  
Alexandria, Virginia 22313-1450

## PRELIMINARY AMENDMENT

Sir:

We are voluntarily amending the national phase application filed herewith for reducing the excess claim fees. Accordingly, please amend the above-identified application as follows:

**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims, which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 5 of this paper.

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**TORONTO MISSISSAUGA WATERLOO MONTREAL**

**Amendments to the Specification:**

Please add the following new paragraph after the title on page 1:

This application is a national phase entry of PCT/CA2004/002158, filed December 20, 2004 which claims priority from U.S. Provisional patent application serial number 60/530,237, filed December 18, 2003.

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Original) A method of lowering elevated plasma total homocysteine (tHcy) levels in a subject with end stage renal disease comprising administering an effective amount of Mesna, or a derivative thereof, to a subject having end stage renal disease (ESRD).
2. (Original) The method according to claim 1, wherein the derivative of Mesna is diMesna.
3. (Currently Amended) The method according to claim 1 ~~or~~ 2, wherein by lowering the tHcy levels in the plasma of a patient with ESRD, the risk of cardiovascular-related diseases is also reduced.
4. (Original) The method according to claim 3, wherein the cardiovascular-related disease is selected from myocardial infarction, stroke, thrombosis and atherosclerosis,
5. (Original) The method according to claim 4, wherein thrombosis is a thrombotic event selected from venous thrombosis, dialysis access thrombosis and thrombotic stroke.
6. (Currently Amended) The method according to ~~any one of~~ claim[[s]] 1[[4]], further comprising performing dialysis on the subject.
7. (Original) The method according to claim 5, wherein the dialysis is performed during or subsequent to administration of Mesna or derivative thereof.

8. (Currently Amended) The method according to ~~any one of claim[[s]] 1[[6]]~~, wherein the subject is human.

9. (Currently Amended) The method according to ~~any one of claim[[s]] 1[[7]]~~ wherein Mesna, or a derivative thereof, is administered at a dosage of about 0.5 – 180 mg/kg per week.

10. (Original) The method according to claim 8, wherein Mesna, or a derivative thereof, is administered at a dosage of about 1.0-25 mg/kg per week.

11. (Original) The method according to claim 9, wherein Mesna, or a derivative thereof, is administered at a dosage of about 7.5-15 mg/kg per week.

12. (Original) The method according to claim 8, wherein Mesna, or a derivative thereof, is administered at a dose of between about 2.5 to 5 mg/kg thrice weekly.

13. (Currently Amended) The method according to ~~any one of claim[[s]] 1[[11]]~~ wherein Mesna, or a derivative thereof, is administered intravenously or orally.

14. (Currently Amended) The method according to ~~any one of claim[[s]] 1[[12]]~~, wherein Mesna, or a derivative thereof, is administered in combination with other agents that lower plasma thiol levels or in combination with other types of treatment for diseases associated with elevated plasma thiol levels.

15. (Original) The method according to claim 13, wherein Mesna, or a derivative thereof, is administered in combination with B vitamins and/or folic acid

16.-18. (Cancelled)

**REMARKS/ARGUMENTS**

This preliminary amendment is filed together with the National Phase Entry of PCT Application PCT/CA2004/002158 for reducing excess claim fees. Accordingly, the Applicants have amended the claims to remove multiple claim dependencies and cancel use claims.

The Applicants have also amended the specification on page 1 to insert a reference to previously filed applications upon which the present application claims priority.

The Applicants submit that the above amendments to this specification and claims do not add new matter to the application. Entry of the above preliminary amendment is respectfully requested.

Respectfully submitted,

BERESKIN & PARR

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